



A repository to support risk assessments of NLS and NIAS

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Food Packaging Forum 2019 Workshop (October 2019)

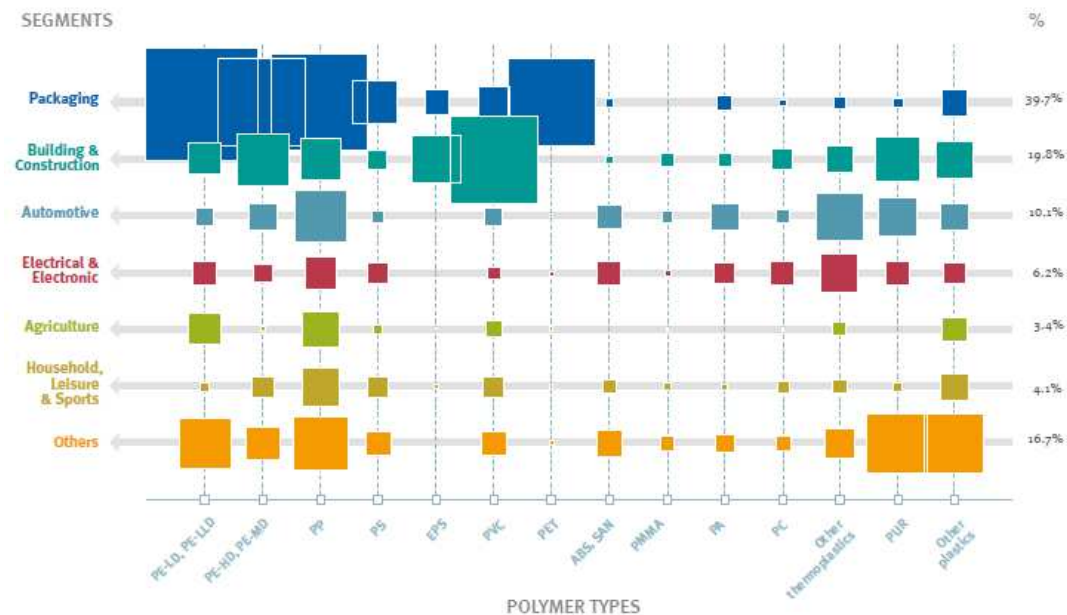
PlasticsEurope
Association of Plastics Manufacturers

European plastics demand by segments and polymer types

European plastic converter demand by segments and polymer types in 2017

Data for EU28+NO/CH.

Source: PlasticsEurope Market Research Group (PEMRG) and Conversio Market & Strategy GmbH



2017 EUROPEAN Plastics converter demand: ~51 millions Tonnes/y
Food Contact Application: > 10-12 millions Tonnes/y (~50% packaging +...)

The EU Food Contact Requirements for plastics (in short)

Article 3

Regulation (EC) 1935/2004

- **must not** under normal or foreseeable conditions:
 - **Endanger human health**
 - Unacceptable change in composition of food
 - Deterioration of organoleptic characteristics

Article 5

Regulation (EC) 10/2011

- Monomers or other starting substances
- Additives excluding colorants
- Polymer production aids excluding solvents
- Macromolecules obtained from microbial fermentation

Article 6.2/6.4

Regulation (EC) 10/2011

- Non-intentionally added substances (NIAS)
 - Aids to polymerization (AP)
 - Colorants and solvents
- } NLS

Article 19

Regulation (EC) 10/2011

- NLS (non-listed substances) and NIAS are subject to a risk assessment acc. to internationally recognized principles

Risk-Assessment according to Article 19

- Guidance for Risk Assessment according to Internationally Recognized Principles
 - https://www.plasticseurope.org/application/files/6215/1704/0232/20141010ra_for_non_listed_substances_and_nias_under_article.pdf;
https://fca.cefic.org/images/FCA_Risk_Assessment_Guidelines_v2.0.pdf;
<https://ilsa.eu/publication/guidance-on-best-practices-on-the-risk-assessment-of-non-intentionally-added-substances-nias-in-food-contact-materials-and-articles/> ; <https://www.who.int/foodsafety/publications/chemical-food/en/>
 - Based on modern scientific approaches, address new concern
 - Progress ahead of regulation and follow modern sciences
 - Use a broad sources of validated data
 - Toxtree, TTC, Peer reviewed scientific literatures, Reach data,...
 - Evaluation from Authorities (EFSA, Member States,...)
 - Industry toxicological studies, Exposure assessments,...
- Challenges
 - Limited recognition at EU enforcement
 - Due to confidentiality and competition, detailed information cannot be easily shared and transferred all along the entire value chain



Suggestion to make the industry human exposure assessments more transparent:
REPOSITORY

REPOSITORY

The aim of the repository:

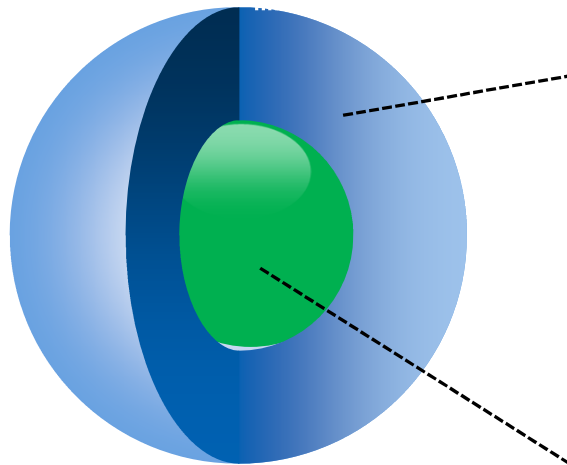
- To make industry the human exposure assessments **more visible**
- To **avoid duplication/multiplication** of assessment work in the value chain
- To **allow data sharing** (and compensation of data) of a specific substance of interest for e.g. risk assessment purposes
- **Creating recognition** of hazard information at enforcement authorities



Without a repository such data would stay isolated and non-standardized in the value chain

Please note that the content of this presentation provides only a brief overview of the ideas developed during brainstorming sessions. The content needs to be further analyzed and developed

General Concept



The repository shall contain information assessed by Industry or Member States, incl. estimated human exposure limits and toxicological endpoints.

Access open to the general public and all stakeholders*

*Packaging and Food industry, Retailers, Importers, National & European authorities, NGO's, Consumers,...

The Core shall contain the detailed assessment by data holder

Access is based on Authorization

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A repository to support communication

Today

Listed Substances: EU “food” limits (e.g. SML’s)
risk evaluation by EFSA and the Commission are generic data
Open to all stakeholders via Annex I of Regulation (EU) No. 10/2011
Communication via Documentation of Compliance (DoC)

Industry substance assessments (Art.19) documented in the supporting documentation (SD)
SD can be accessed by enforcement authorities
Risk Management Measures (RMM) (when applicable) communicated via the DoC

Future ...

Substance evaluations stored in a repository

- General information open to stakeholders including general public
- Detailed human exposure assessment only accessible via Authorization
- All repository information accessible to enforcement authorities
- Ownership of data stays in the repository community

Pilot phase development

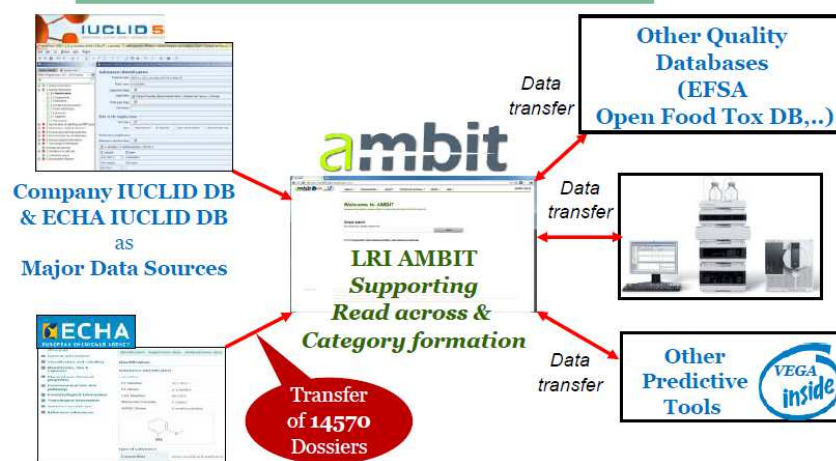
- Dedicated to plastic at starting phase
 - Involvement of the all Plastics Food Contact Industry via Plastics Coordination Group (PCG)*
- Organization (work in progress)
 - Supervisory board: Defining the scene and overviewing the process
 - Project team: Making the repository idea a reality
- Many challenges to be overcome
 - Database model/ownership
 - Substance identity/retrieval
 - Data quality/consistency, ownership, data sharing
 - Liability, misuses, copyright, protection of confidential business information
 - Business model & Cost sharing
 - Authorities participation
- Timeline: Not yet defined

PCG is a think-tank for regulatory topics of the plastics Food Contact Material and Article Value chain composed of CEFIC-FCA, PlasticsEurope, EuPC, Flexible Packaging Europe (FPE), PRE (Plastics Recycling Europe), APPLIA

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Example of existing tools

LRI AMBIT2 Chemoinformatics System: ECHA staff trained!



<http://cefic-lri.org/toolbox/ambit2/>

AMBIT2 main functions

- **Search structures & Data**
 - exact, similar, substructure
 - combined with data search
- **Retrieval and management of IUCLID6 substance data** New
 - substance identification and composition
 - Assigning structures to constituents, impurities
 - 43 data endpoints of 14.570 substances New
- **Read across/category formation**
 - Workflows facilitates search for target and source structures, generating data matrices, gap filling and generating assessment reports with predefined formats automatically
- **Prediction tools / databases** New
 - VEGA models, Toxtree, Cramer rules, Protein binding / OpenFoodToxDB New
- **Data management & exchange**
 - flexible import/export of dataset
 - manual upload of **i6z files**, exported from IUCLID or semi-automatic import via IUCLID Web services.

AMBIT3 ?

- **CompTox Dashboard** database from US EPA (700k chemicals)
- **TK integration (IndusChemFate?, others), ADME's**
- **FAME2 (Univ.Hamburg):** predictive metabolism e-tool
- Open source, Application Programming Interface available
- Stand alone and web versions
- IUCLID n+1 New and better functionalities
- Platform/hub?
- 2019?
- And more...(REACH post 2018, METEOR, ToxRevDB-USEPA, PBT profiler, DIAMONDS, EPISUITE, ...)
- ? Belgian Food Contact Database

Risk Assessment: in Short

https://www.plasticseurope.org/application/files/2615/2933/0926/The_Role_of_Food_Packaging_2018.pdf

Inside Food Contact Materials

WHAT YOU NEED TO KNOW

Plastic Food Contact Materials play a crucial role in preserving food from contaminants and preventing food waste. Yet, some worry about the chemicals that are required in the production of these important materials.

What are Food Contact Materials?

"Food Contact Materials", or FCMs for short, refers to all materials that come into contact with food.

Natural migration occurs whenever two materials come into contact with each other

Migration is a natural and unavoidable phenomenon that occurs in all materials. Whenever two materials come into contact with each other, substances can migrate from one material into another. This also happens with food packaging and food.

Risk assessments make sure that Food Contact Materials are safe

A risk assessment is based on different elements to assess potential health risks associated with exposure to substance migration into the food.

HAZARD IDENTIFICATION: Identifies potential health effects in humans and/or environment, caused by chemicals.

EXPOSURE ASSESSMENT: Evaluates the potential chemical exposures to humans and the environment from the production, distribution, use, disposal and recycle of a chemical substance.

RISK CHARACTERIZATION: Integrates the hazard identification and assessment results to determine the occurrence of health and/or environmental effects in a given population.

THE RESULT ENSURES SAFE USE

Quantity is key

Even natural substances can interact with the body but would only cause adverse effects from a certain dose. It is the quantity which sets the risk.

Water: Water is vital for leading a healthy lifestyle. We need water to remain hydrated and energetic.

Water intoxication can occur when a person drinks so much that the water dilutes the concentration of sodium in the blood, causing an electrolyte imbalance. Water intoxication, however an infrequent occurrence, is mostly a risk for endurance athletes.

Adequate Daily Intake: around 2.5 litres!

Coffee: Coffee has antioxidants and nutrients that contribute to good health. Coffee increases your focus and can improve energy levels.

ADK: 400 milligrams!

Too much caffeine can cause nervousness, restlessness, nausea, irregular heartbeat, muscle tremor, anxiety and headaches.

Soy sauce: Soy sauce has some great health benefits: it is low in calories and very high in natural antioxidants.

ADK: 2 tablespoons (32 grams)!

Why is it a problem as well...

In a sustainable society, using modern packaging and storage systems, waste is reduced dramatically to around 3%.

HOW CAN WE ENSURE THAT THEY ARE SAFE?

A SCIENCE-BASED ANALYSIS IS PERFORMED TO ENSURE THE SAFE USE OF AN ADDED SUBSTANCE

1 Identify and physico-chemical properties of the substances

The goal is to understand the substance and how it migrates. The applicant provides information on the basic properties (e.g. solubility and stability) and explains the first use of the substance, including: maximum use level, function, in which plastics, in contact with which foods, what are the contact conditions (time, temperature, ...), etc.

2 Data on the residual content of the substance in the Food Contact Material

The objective is to understand how much of the substance is present and what type of specific migration can be expected.

3 Migration data of the substance

The purpose is to comprehend how much of a substance is migrating into food. This is done by testing different types of food and real storage conditions (time/temperature).

4 Toxicological data and microbiological properties of the substance

The applicant needs to demonstrate that, in case of microbiological properties of a substance, these have no effect on the food. To demonstrate that levels of migration into food are safe for human consumption, the applicant provides the adequate toxicological reports.

5 Evaluation of existing assessments

The applicant provides information on whether a substance is already approved in a consumer application elsewhere.

Conclusions

EFSA reports its conclusions to the European Commission. If approved, the substance can be used in FCMs. The substance is safe and suitable to be used in food contact according to the descriptors included in the technical dossier.

THANKS for your attention

Others in development